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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,838	08/24/2006	Christina Blaschke	47082-115USPX	1432

71331 7590 05/27/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
2856	

MAIL DATE	DELIVERY MODE
05/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,838	BLASCHKE ET AL.	
	Examiner	Art Unit	
	DANIEL S. LARKIN	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6 and 8-27* is/are rejected.

7)☒ Claim(s) *3 and 7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/12/07 & 02/04/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. Reference to WO 2005/078436 has been considered; but, because this document forms the basis for priority for the instant application, this document is not deemed to be "PRIOR ART" for use in the application.

Additionally, select foreign references cited on Page 2 of the Information Disclosure Statement (IDS) filed 12 February 2007 have been considered, but crossed-out because these references have been duplicated from Page 1 of same IDS.

3. The information disclosure statement filed 12 February 2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein, specifically DE 69208419, has not been considered.

Applicants are advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all

certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

4. The drawings are objected to because of the following:

Reference Figure 1: The curly bracket or brace "{" shown should be referencing reference numeral 10 rather than the designation "Fig. 1"

Reference Figure 4a: The lead line representing reference numeral "52" on the left-hand side of the figure appears to be pointing to the sub-electrode portion of the electrode, rather than the spacer edge.

Reference Figure 5b: The figure appears to show the leading edge 46 of the fluid as the outer edge 40 of the second electrode 20; however, the specification fails to make reference to outer edge of the electrode 20 with respect to Figures 5a-d.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

Reference numeral "48" does not appear within Figures 4a-c as suggested by the disclosure on page 5, lines 6-7.

Reference numeral "46" does not appear within Figures 5b as suggested by the disclosure on page 6, line 10.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Reference numeral "40", as shown in Figure 5b, does not appear within the specification as the description relates to this particular figure.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the Applicants will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The disclosure is objected to because of the following informalities:

Page 6, lines 3, 6, and 25: Reference numeral "58" should be corrected to read -- 58a-b --. Appropriate correction is required.

Claim Objections

9. Claims 25 and 26 are objected to because of the following informalities:

Re claim 25, claim line 3: The phrase "said electrode" lacks antecedent basis. The phrase "said electrode" should be corrected to read -- said electrode layer --. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 8-14, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,798,031 (Charlton et al.).

With respect to the limitations of claims 1 and 8-10, Charlton et al. disclose an electrochemical biosensor, comprising: a sample cavity (48) for accepting sample fluid; at least one test region disposed along the sample cavity; and at least one vent (50) for venting the sample cavity, the at least one vent (50) having at least one sample guide edge for guiding the sample fluid to the at least one test region. Charlton et al. further disclose that the test region is selected from the group of an electrode (39, 40) and a

reagent area (44). Moreover, the test region comprises two electrodes (39, 40). Additionally, a dielectric material (42) covers the two electrodes (39, 40).

With respect to the limitations of claims 11-14, Charlton et al. disclose a method for collecting sample fluid and positioning sample fluid in a test sensor for analysis of said sample fluid, comprising the steps of: accepting a sample fluid within a sample cavity (48) via capillary action; and directing the sample fluid through the sample cavity toward at least one test region of the sensor using at least one sample guide edge provided on at least one vent (50) venting the sample cavity. The sample fluid is accepted at a fluid inlet area; and the at least one test region is selected from the group consisting of an electrode (39, 40) and a reagent area (40). Moreover, the at least one test region is comprised of two electrodes (39, 40).

With respect to the limitations of claim 27, Charlton et al. disclose an electrochemical biosensor, comprising: a sample cavity (48) having a fluid inlet area, the sample cavity adapted for being filled via capillary action and having a vent (50), the vent having at least one sample guide edge for guiding fluid under capillary action within the sample cavity during filling of the sample cavity.

12. Claims 1, 8-14, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 537761 (Yoshioka et al.).

With respect to the limitations of claims 1 and 8-10, Yoshioka et al. disclose a biosensor, as shown in Figures 6 and 7, comprising: a sample cavity for accepting sample fluid, col. 13, lines 8-11; at least one test region disposed along the sample cavity, col. 13, lines 11-14; and at least one vent (24, 28) for venting the sample cavity,

the at least one vent (24, 28) having at least one sample guide edge for guiding the sample fluid to the at least one test region. Yoshioka et al. further disclose that the test region is selected from the group of an electrode (6, 7) and a reagent area (50). Moreover, the test region comprises two electrodes (6, 7). Additionally, a dielectric material (10) covers the two electrodes (6, 7).

With respect to the limitations of claims 11-14, Yoshioka et al. disclose a method for collecting sample fluid and positioning sample fluid in a test sensor for analysis of said sample fluid, comprising the steps of: accepting a sample fluid within a sample cavity via capillary action; and directing the sample fluid through the sample cavity toward at least one test region of the sensor using at least one sample guide edge provided on at least one vent (24, 28) venting the sample cavity, col. 13, lines 8-14. The sample fluid is accepted at a fluid inlet area/port (23); and the at least one test region is selected from the group consisting of an electrode (6, 7) and a reagent area (50). Moreover, the at least one test region is comprised of two electrodes (6, 7).

With respect to the limitations of claims 25 and 26, Yoshioka et al. disclose a biosensor, comprising: a base layer (1); an electrode layer (19, 20) supported by the base layer, the electrode layer having a first electrode (6, 8) and a second electrode (7, 9), the first and second electrodes respectfully extending from first and second electrode leads (12, 13 and 14, 15) and having central portions; a cover layer (21, 29) disposed above the electrode layer (19, 20), the cover layer having a projection defining a sample cavity; a fluid inlet area/port (23, 27) in fluid communication with said sample cavity; and first and second vents (24, 28), the first vent (24) having a first guide edge and the second vent (28) having a second guide edge opposing the first guide edge, the

first and second guide edges opposing each other above at least one of the central portions of the first and second electrodes. Additionally, the electrodes have central portions, an intermediate area between said first and second opposing guide edges being disposed above one of the central portions of the electrodes.

With respect to the limitations of claim 27, Yoshioka et al. disclose a biosensor, comprising: a sample cavity having a fluid inlet area/port (23, 27), the sample cavity adapted for being filled via capillary action and having a vent (24, 28), the vent having at least one sample guide edge for guiding fluid under capillary action within the sample cavity during filling of the sample cavity, col. 13, lines 8-14.

13. Claims 1, 8-15, and 25-27 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/012421 (Yoshida et al.).

With respect to the limitations of claims 1 and 8-10, Yoshida et al. disclose a analyzing implement, as shown in Figures 2 and 3, comprising: a sample cavity (6, 60) for accepting sample fluid; at least one test region disposed along the sample cavity; and at least one vent (51-53) for venting the sample cavity, the at least one vent (51-53) having at least one sample guide edge (61-63) for guiding the sample fluid to the at least one test region. Yoshida et al. further disclose that the test region is selected from the group of an electrode (31, 32) and a reagent area (36). Moreover, the test region comprises two electrodes (31, 32). Additionally, a dielectric material (4) covers the two electrodes (31, 32).

With respect to the limitations of claims 11-15, Yoshida et al. disclose a method for collecting sample fluid and positioning sample fluid in a test sensor for analysis of

said sample fluid, comprising the steps of: accepting a sample fluid within a sample cavity via capillary action; and directing the sample fluid through the sample cavity toward at least one test region of the sensor using at least one sample guide edge (61-63) provided on at least one vent (51-53) venting the sample cavity. The sample fluid is accepted at a fluid inlet area (42); and the at least one test region is selected from the group consisting of an electrode (31, 32) and a reagent area (36). Moreover, the at least one test region is comprised of two electrodes (6, 7).

With respect to the limitations of claims 25 and 26, Yoshida et al. disclose a biosensor, comprising: a base layer (3); an electrode layer supported by the base layer, the electrode layer having a first electrode (31) and a second electrode (32), the first and second electrodes respectfully extending from first and second electrode leads (32) and having central portions; a cover layer (4) disposed above the electrode layer, the cover layer having a projection (40) defining a sample cavity; a fluid inlet area (42) in fluid communication with said sample cavity; and first and second vents (51-53), the first vent (51) having a first guide edge and the second vent (52) having a second guide edge opposing the first guide edge, the first and second guide edges opposing each other above at least one of the central portions of the first and second electrodes. Additionally, the electrodes have central portions, an intermediate area between said first and second opposing guide edges being disposed above one of the central portions of the electrodes.

With respect to the limitations of claim 27, Yoshida et al. disclose a biosensor, comprising: a sample cavity having a fluid inlet area (42), the sample cavity adapted for being filled via capillary action and having a vent (51-53), the vent having at least one

sample guide edge for guiding fluid under capillary action within the sample cavity during filling of the sample cavity.

14. Claims 1, 2, 4-6, and 8-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,120,420 (Nankai et al.).

With respect to the limitations of claims 1 and 8-10, Nankai et al. disclose a biosensor, as shown in Figures 12 and 13, comprising: a sample cavity (8 or 81, 82) for accepting sample fluid; at least one test region disposed along the sample cavity; and at least one vent (11-13 or 11, 12) for venting the sample cavity, the at least one vent (11-13 or 11, 12) having at least one sample guide edge for guiding the sample fluid to the at least one test region. Nankai et al. further disclose that the plurality of vents (11-13) have aligned sample guide edges. Alternatively, Nankai disclose that the at least one vent (11-13) comprise two staggered vents spaced apart from each other to form a tortuous fluid pathway within the sample cavity, and a reagent layer in communication with the sample cavity. Nankai et al. further disclose that the test region is selected from the group of an electrode (41-43) and a reagent area, col. 8, lines 11-14. Moreover, the test region comprises two electrodes (31, 32). Additionally, a dielectric material (7) covers the two electrodes (41-43).

With respect to the limitations of claims 11-17, Nankai et al. disclose a method for collecting sample fluid and positioning sample fluid in a test sensor for analysis of said sample fluid, comprising the steps of: accepting a sample fluid within a sample cavity via capillary action; and directing the sample fluid through the sample cavity toward at least one test region of the sensor using at least one sample guide edge

provided on at least one vent (11-13 or 11, 12) venting the sample cavity. The sample fluid is accepted at a fluid inlet area (10); and the at least one test region is selected from the group consisting of an electrode (41-43) and a reagent area, col. 8, lines 11-14. Moreover, the at least one test region is comprised of two electrodes (41-43). Nankai et al. further disclose that the two vents are placed at staggered positions within along the sample cavity and further comprising directing the sample fluid along a fluid pathway; and wherein the sensor is provided with a reagent disposed along the sample cavity, wherein the fluid pathway is tortuous, and further comprising mixing the test fluid with the reagent as the sample fluid is directed along the fluid pathway.

With respect to the limitations of claims 23 and 24, Nankai et al. disclose a biosensor, comprising: a sample cavity (8) for accepting sample fluid, the sample cavity having an fluid inlet (10); first and second vents (13, 12) within the sample cavity, the first and second vents having respective first and second vent edges and being disposed along a fluid pathway of the sample cavity such that the first vent (13) is closer to the fluid inlet (10) than the second vent is; a first reagent area disposed along the sample cavity beneath said first vent (13), col. 8, lines 11-14; and a second reagent area disposed along the sample cavity beneath the second vent (12), col. 8, lines 11-14.

Nankai et al. further disclose that the first and second vents (13, 12) are spaced along the fluid pathway such that sample fluid entering the fluid inlet (10) contacts the first and second vent edges in succession. Additionally, the sensor is designed whereby the first reagent is adapted to react with the sample fluid for a first optimum reaction time and the second reagent is adapted to react with the sample fluid for a second optimum reaction time, the second optimum reaction time being less than the

first optimum reaction time because the a sample fluid must travel a tortuous path prior to reaching the vents. Nankai et al. also disclose an additional vent (11) having vent edges and being disposed along said fluid pathway and additional reagent areas disposed along the sample cavities respectively beneath the additional vent, col. 8, lines 11-14.

With respect to the limitations of claims 23 and 24, Nankai et al. disclose a method for analyzing a fluid sample, comprising: accepting said sample fluid within a sample cavity via capillary action, the sample cavity having a fluid inlet (10) and first and second vents (11-13) disposed along a fluid pathway, the sample cavity further having a first reagent disposed beneath said first vent and a second reagent disposed beneath said second vent, col. 8, lines 11-14; the first and second vents having first and second vent edges; guiding said fluid sample along said fluid pathway via capillary action such that the fluid passes the first vent before passing the second vent; and filling the sample cavity (8) such that the sample fluid first fills a first volume beneath the first vent and later fills a second volume beneath the second vent. Nankai appears to provide a time delay between the time at which the sample fluid fills the first volume beneath the first vent and the time at which the sample fluid fills the second volume beneath the second vent is greater than about three seconds, by providing a tortuous path for the sample fluid to flow in order to reach each vent.

With respect to the limitations of claims 25 and 26, Nankai et al. disclose a biosensor, comprising: a base layer (1); an electrode layer supported by the base layer, the electrode layer having a first electrode (41) and a second electrode (42), the first and second electrodes respectfully extending from first and second electrode leads (21,

22) and having central portions; a cover layer (7) disposed above the electrode layer, the cover layer having a projection defining a sample cavity (8, 81, 82); a fluid inlet area (10) in fluid communication with said sample cavity; and first and second vents (11-13, or 11, 12), the first vent (11) having a first guide edge and the second vent (12) having a second guide edge opposing the first guide edge, the first and second guide edges opposing each other above at least one of the central portions of the first and second electrodes. Additionally, the electrodes have central portions, an intermediate area between said first and second opposing guide edges being disposed above one of the central portions of the electrodes.

With respect to the limitations of claim 27, Nankai et al. disclose a biosensor, comprising: a sample cavity having a fluid inlet area (10), the sample cavity adapted for being filled via capillary action and having a vent (11-13), the vent having at least one sample guide edge for guiding fluid under capillary action within the sample cavity during filling of the sample cavity.

Allowable Subject Matter

15. The following is a statement of reasons for the indication of allowable subject matter:

Prior art was not relied upon to reject claims 3 and 7 because the prior art fails to teach and/or make obvious the limitations of the above cited claims in combination with all of the limitations of the base claims and all intervening claim.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL S. LARKIN whose telephone number is (571)272-2198. The examiner can normally be reached on 8:30 AM - 5:00 PM Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel S. Larkin/
Primary Examiner, Art Unit 2856
21 May 2008